

REMARKS

Claims 8-38 were canceled, and claim 39 has been withdrawn. Therefore, claims 1-7 and 39-41 are pending in the captioned application. Further examination and reconsideration of claims 1-7 and 39-41 are respectfully requested.

Section 112, second paragraph, Rejections

Claims 1-7, 40, and 41 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant respectfully traverses these rejections.

For at least the reasons set forth in the Amendment; Response filed in the present case by Applicant on March 25, 2005 (hereinafter "the prior response"), which is incorporated by reference as if fully set forth herein, claims 1-7, 40, and 41 are definite. Nevertheless, the § 112, second paragraph, rejections of claims 1-7, 40, and 41 have been maintained. Rebuttal arguments set forth in detail below address specifically the rationale presented in the Final Office Action for maintaining the § 112, second paragraph, rejections of claims 1-7, 40, and 41.

The Final Office Action states:

Claims 1 and 7 continue to recite "one reagent designed to interact selectively with a pre-determined analyte". It remains unclear what the metes and bounds of "selectively" are in the claim. Applicant has pointed to several pieces of prior art to support the argument that "the term 'interact selectively' is known in the art". Furthermore, Applicant states that "the term is not assigned any special meaning in the specification". It is evident that from the various pieces of prior art that "selectively" can mean a number of things. Without clarification of the metes and bounds intended by Applicant, the term remains indefinite and the rejection is maintained. (Final Office Action -- pages 2-3).

Applicant respectfully traverses this assertion.

Even if the term "interact selectively" can have a number of meanings according to the teachings of the prior art, since the term is not assigned a special meaning in the specification, the term "interact selectively" can have any of these meanings. A fundamental principle contained in 35 U.S.C. 112, second paragraph is that applicants are their own lexicographers. They can define in the claims what they regard

as their invention essentially in whatever terms they choose so long as any special meaning assigned to a term is clearly set forth in the specification. MPEP 2173.01.

The Examiner appears to be equating breadth of a claim term with indefiniteness. However, even if a claim term such as "interact selectively" is broadly defined in the teachings of the prior art, breadth of claim terminology does not render the claim indefinite. A claim cannot be rejected as indefinite simply because it is broad in scope. Breadth of a claim is not to be equated with indefiniteness. *In re Miller*, 441 F.2d 689, 169 USPQ 597 (CCPA 1971). MPEP 2173.04.

Since the scope of the subject matter embraced by claims 1 and 7 is clear for at least the reasons set forth above, and since Applicants have not otherwise indicated that they intend the invention recited in claims 1 and 7 to be of a scope different from that defined in the claims, claims 1 and 7 comply with 35 U.S.C. 112, second paragraph. If the scope of the subject matter embraced by the claims is clear, and if applicants have not otherwise indicated that they intend the invention to be of a scope different from that defined in the claims, then the claims comply with 35 U.S.C. 112, second paragraph. MPEP 2173.04. As such, the term "interact selectively" does not render claims 1 and 7 indefinite.

For at least the reasons set forth above, claims 1-7, 40, and 41 are definite since these claims particularly point out and distinctly claim the subject matter which applicant regards as the invention. As such, removal of the § 112, second paragraph, rejections of claims 1-7, 40, and 41 is respectfully requested.

Section 103(a) Rejections

Claims 1-7, 40, and 41 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Kettman et al. (Cytometry (1998) 33:234-243) (hereinafter "Kettman") in view of Ekins (Journal of Pharmaceutical and Biomedical Analysis (1989) 7: 155-168) (hereinafter "Ekins"). The § 103(a) rejections of claims 1-7, 40, and 41 are respectfully traversed.

For at least the reasons set forth in the prior response, the Examiner has failed to establish a *prima facie* case of obviousness based on the combination of Kettman and Ekins. Nevertheless, the § 103(a) rejections of claims 1-7, 40, and 41 have been maintained. Rebuttal arguments set forth in detail below

address specifically the rationale presented in the Final Office Action for maintaining the § 103(a) rejections of claims 1-7, 40, and 41.

The Examiner again has failed to establish a *prima facie* case of obviousness. To establish a *prima facie* case of obviousness, three basic criteria must be met...there must be a reasonable expectation of success...the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991). MPEP 2142. The prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). MPEP 2143.02.

The Final Office Action states that "the rejection is based upon obviousness and Ekins et al. is relied upon to teach more than 64 sets in analyte analysis." (Final Office Action – pages 4-5). Applicant respectfully traverses this assertion.

In particular, Ekins does not teach "more than 64 sets" or any sets for that matter as the term "sets" is defined in the teachings of Kettman. For instance, Kettman teaches that sets are microsphere sets. In addition, the present claims recite "subsets of microspheres." Therefore, in the context of the present case, the term "set" refers to a set of microspheres.

Ekins, however, does not teach any microspheres at all. For instance, Ekins teaches different antibodies distributed over a single surface, each of which is specific to a different analyte being examined. Ekins teaches that the different analytes are individually labeled (i.e., by having a label attached to the antibodies themselves) such that the different analytes can be differentiated. Therefore, Ekins teaches more than 64 different antibodies, each coupled to the same surface, but Ekins clearly does not teach "more than 64 sets in analyte analysis" as contended in the Final Office Action. Consequently, Ekins cannot be relied upon to teach more than 64 sets that can be used in analyte analysis. As such, this basis for the obviousness rejections of the present claims is improper.

The Final Office Action states that "The arguments are not persuasive, as the instant claims have no limitations regarding 'how fluorescence is imparted'. Therefore, the markers being coupled or not is of no relevance to what is instantly claimed. Applicant is again reminded that Eikens et al. is relied upon solely to teach that more than 64 sets may be used in analyte analysis, with a reasonable expectation of

success, as previously set forth." (Final Office Action -- page 5). Applicant respectfully traverses this assertion.

As set forth above, Ekins does not teach more than 64 sets that can be used in analyte analysis. Therefore, Ekins cannot teach that more than 64 sets can be used in analyte analysis with reasonable expectation of success.

Regardless of how fluorescence is imparted to the presently claimed subsets of microspheres, the manner in which fluorescence is imparted to the assays in the prior art must be considered by the Examiner to determine if reasonable expectation of success is taught or suggested by the prior art for "more than 64 sets." In particular, the prior art references must be considered in their entirety. A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984). MPEP 2141.02. Therefore, the Examiner cannot arbitrarily select portions of the prior art references to reject the present claims without considering what the combined teachings of the prior art as a whole suggest to one of ordinary skill in the art.

Since Kettman teaches that "The vehicle for each separate measurement consists of a set of microspheres identifiable by characteristic fluorophores embedded in the particles" (Kettman -- page 234), the manner in which fluorescence is imparted is particularly relevant to the question of whether or not the prior art teaches or suggests reasonable expectation of success for more than 64 sets that can be used in analyte analysis. Kettman specifically teaches that the dyes used for discrimination of different microsphere sets are dissolved into the microspheres. In contrast, Ekins specifically teaches that the dyes used for discrimination of different analytes (e.g., antibodies) are attached directly to the analytes themselves. In addition, Ekins teaches that the different analytes are differentiated from one another based on the ratio of the fluorescent labels attached to two analytes involved in a reaction with an antigen. As such, Kettman and Ekins use dramatically different technologies for fluorescent-based discrimination of analytes. In addition, as known by one possessing the ordinary level of skill in the art at the time the invention was made, the technology for coupling fluorescent labels to antibodies cannot be used to dissolve fluorescent labels into a microsphere.

Since Ekins teaches that analyzing tens or hundreds of analytes is feasible using a technology different than the technology taught by Kettman, Ekins does not teach or suggest that using more than 64

microsphere sets for analyte analysis is technically feasible. Furthermore, Ekins does not teach or suggest that measuring tens or hundreds of analytes is technically feasible using the microsphere sets taught by Kettman. Moreover, since the teachings of Ekins do not even mention microspheres or microsphere sets, Ekins cannot teach or suggest that measuring tens or hundreds of analytes is technically feasible using microspheres or microsphere sets. As such, Ekins cannot teach or suggest reasonable expectation of success for using more than 64 sets for analyzing analytes. Therefore, Ekins does not teach or suggest that more than 64 sets can be used in analyte analysis with any reasonable expectation of success as contended in the Final Office Action.

Even if the fluorescent markers of Ekins could be coupled to the surface of the microspheres of Kettman, Kettman does not teach or suggest reasonable expectation of success for such modification of the microspheres of Kettman. In particular, the teachings of Kettman do not teach or suggest reasonable expectation of success for attaching fluorescent-based labels to a surface of the microspheres to distinguish the microspheres of one set from those of another. For instance, Kettman states that "Because the dyes are inside the microspheres, solvent conditions will not affect the dye characteristics." (Kettman -- page 241, col. 1). Therefore, according to the teachings of Kettman, if the fluorescent-based labels of Ekins are attached to a surface or a reagent on a surface of the microspheres (i.e., external to the microspheres), the solvent conditions will affect the dye characteristics of the microspheres thereby decreasing the uniformity of the fluorescence of microspheres in a set. In addition, Kettman teaches that non-uniformity of fluorescence limits how many microsphere sets can be used in an assay. Therefore, Kettman teaches that attaching the fluorescent based labels of Ekins to the surface of the microspheres of Kettman increases the non-uniformity of the fluorescent characteristics of the microspheres thereby reducing the number of microsphere sets that can be used in the assay. As such, Kettman does not teach or suggest reasonable expectation of success for applying the technology taught by Ekins to the microspheres of Kettman to produce more than 64 sets that can be used in analyte analysis.

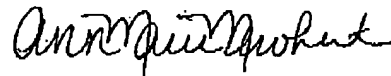
For at least the reasons set forth above, no reasonable expectation of success is found in the prior art. Consequently, at least one of the criteria for establishing a *prima facie* case of obviousness has not been met. Accordingly, removal of the § 103 rejections of claims 1-7, 40, and 41 is respectfully requested.

CONCLUSION

This response constitutes a complete response to all issues raised in the Final Office Action mailed June 29, 2005. In view of the remarks presented herein, Applicants assert that pending claims 1-7 and 39-41 are in condition for allowance. If the Examiner has any questions, comments, or suggestions, the undersigned earnestly requests a telephone conference.

The Commissioner is authorized to charge any required fees or credit any overpayment to deposit account number 50-3268/5868-02801.

Respectfully submitted,



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